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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/673,739 | 10/20/2000 | Thomas Valentine McCarthy | 1377-156P | 3757 |

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EXAMINER

TUNG, JOYCE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

DATE MAILED: 02/08/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/673,739

Applicant(s)
McCarthy et al.

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 26, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Response to Amendment

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

2. The amendment filed 11/26/2001 has been entered.

3. Regarding the double patenting rejection of claims 1-5, 8, 10-12, 14-16 and 20-23 over claims 1, 2, 4-7, 12-13 and 15-19 of U.S. Pat. No. 5,952,176 in view of Chirikjian et al.

Applicants's argument is focused on the difference between the references of Chirikjian et al. and the step iv) of claim 1 as set forth on page 4 of the response. However, as indicated in the response that U.S. '430 teaches the use of a template and polymerase extension, i.e. that DNA containing a 3' OH terminus can be extended with polymerase and/or ligase enzyme using a template to direct the extension, and this feature was well known in the art (See pg. 4, first paragraph of the response) (See fig. 2 of U.S. Pat. No. 5,656,430). This feature suggests the step iv) of claim 1. Applicants further argue that claim 1 has been amended to explicitly recite that an "additional" template nucleic acid is used to distinguish the teachings of Chirikjian et al. but the phrase "an additional template" on lines 12-13 is nonsequitur because it is unclear whether or not the template is a new template or the same template used before. Thus, the rejection is maintained.

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4. Claims 1-5, 8, 10-12, 14-16, 20-21 and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7, 12-13, 15-19 of U.S. Patent No. 5,952,176 in view of Chirikjian et al. (5,656,430).

5. The objection of the specification is withdrawn because of the newly submitted Abstract.

6. The objection of claim 22 is withdrawn because of the cancellation of claim 22.

7. Regarding the rejection of claims 1-23 under 35 U.S.C. §112, second paragraph, the rejections of claims 1-23 in section 6 (a)-(c) of the Office action mailed 7/05/2001 are withdrawn because of the amendment. The rejection of claim 19 in section 6(d) is maintained because based upon Applicants' argument, it is still unclear what is meant by "the reporter oligonucleotide is partially degenerated".

6. Claim 19 is vague and indefinite because the language "the reporter oligonucleotide is partially degenerate". It is unclear how the language is defined in the specification.

7. Regarding the rejection of claims 1-2 and 8-23 under 35 U.S.C. §103(a) over McCarthy et al. (WO 97/03210) in view of Chirikjian et al. (5,656,430), as discussed in section 3 above, the rejection is maintained.

8. Claims 1-2, 8-21 and 23 are rejected under 35 U.S.C. §103(a) as being unpatentable over McCarthy et al. (WO 97/03210) in view of Chirikjian et al. (5,656,430).

9. Regarding the rejection of claims 3-7 under 35 U.S.C. §103(a) over McCarthy et al. (WO 97/03210) in view of Chirikjian et al. and Dianov et al., Applicants argue that Dianov et al. fail to teach that an upstream fragment is formed by cleaving the DNA at an abasic site and

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extending it. However, Dianov et al. teach the way to cleave nucleic acid fragment which is the same steps as claimed in claims 3-6 (See pg. 1606, fig.1) and the fragment with a 3' hydroxyl terminus is extended by polymerase (See pg. 1606, fig. 1). In addition, with the same reason as indicated in section 3 above, the rejection is maintained.

10. Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarthy et al. (WO 97/03210) in view of Chirikjian et al. (5,656,430) as applied to claims 1-2, 8-21, and 23 above, and further in view of Dianov et al. (Molecular and Cellular Biology, 1992, Vol. 12(4), pg. 1605-1612).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-21 and 23 are vague and indefinite because the phrase “an additional template nucleic acid” in claim 1 is nonsequitur.

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

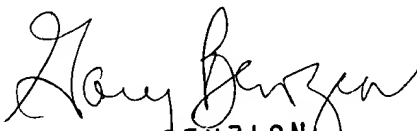
Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

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15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

February 7, 2002


GARY BENZION
SUPERVISORY PATENT
EXAMINER
TC 1600